October 5, 2006

Donald A. Lederer, Jr.
Regulatory Compliance Specialist
Huntsman Petrochemical Corporation
10003 Woodloch Forest Drive
The Woodlands, Texas 77380

Dear Mr. Lederer:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Ethylene Carbonate, posted on the ChemRTK HPV Challenge Program Web site on May 6, 2005. I commend Huntsman Petrochemical Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Huntsman Petrochemical advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/S/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: R. Lee
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Ethylene Carbonate

Summary of EPA Comments

The sponsor, Huntsman Petrochemical Corporation, submitted the test plan and robust summaries to EPA for Ethylene Carbonate (CAS No. 96-49-1) dated April 18, 2005. Data were also provided for the proposed supporting chemical, ethylene glycol (CAS No. 107-21-1). EPA posted the submission on the Chemical RTK HPV Challenge Web site on May 5, 2005.

EPA has reviewed the submission and has reached the following conclusions:

1. Analog Justification. Ethylene glycol, a metabolite of ethylene carbonate, is an adequate analog for the mammalian toxicity endpoints. EPA reserves judgement on its use for the ecotoxicity endpoints.

2. Physicochemical Properties. The submitter needs to correct the vapor pressure robust summary value.

3. Environmental Fate. EPA agrees with the submitter's proposal to provide measured stability-in-water data. The submitter needs to provide the input values for its fugacity estimations.

4. Health Effects. The submitter needs to provide available ethylene glycol data to address the genetic toxicity/chromosomal aberrations endpoint.

5. Ecological Effects. Data for invertebrates are adequate for the purposes of the HPV Challenge Program. EPA reserves judgement on the submitted ethylene glycol data for the fish and algae toxicity endpoints pending submission of data for stability in water (the submitted cyanobacteria data do not address the algal toxicity endpoint). The submitter needs to address deficiencies in the robust summary for invertebrate toxicity.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on Ethylene Carbonate Challenge Submission

Test Plan

Analog Justification

The submitter provided data demonstrating that ethylene carbonate is metabolized to ethylene glycol following gavage administration to rats. EPA agrees with the submitter's proposal to use data for ethylene glycol to address data gaps for the mammalian toxicity endpoints. EPA reserves judgement on the use of ethylene glycol data for ecotoxicity endpoints pending the submission of stability-in-water data for ethylene carbonate to clarify whether and how rapidly the glycol forms under test conditions.

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility)

The submitted data for melting point, boiling point, octanol/water partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Vapor pressure. The robust summary value is 1.307 hPa, or 0.98 mm Hg. However, the reference provided gives a value of 9.8×10^{-3} mm Hg at 25 °C (0.0098 mm Hg). This discrepancy need correction.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The submitted data for photodegradation and biodegradation are adequate for the purposes of the HPV

Challenge Program. EPA agrees with the submitter that existing stability-in-water data are inadequate and that testing is needed following OECD TG 111.

Fugacity. The submitter needs to include in the fugacity section the input values used in its estimation for the Fugacity Level III Model.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitter provided adequate data for the acute, repeated-dose, genetic toxicity (gene mutations) and reproductive/developmental toxicity endpoints for the purposes of the HPV Challenge Program.

Genetic toxicity (chromosomal aberrations). The submitter provided data for this endpoint from a dominant lethal assay on ethylene glycol. EPA does not consider the dominant lethal assay an adequate substitute for chromosomal aberration tests. For more studies, EPA refers the submitter to the report on ethylene glycol and propylene glycol by the U.S. Department of Health and Human Services (Toxicological Profile of ethylene glycol and propylene glycol, 1997) and the CICADS document on ethylene glycol (http://www.inchem.org/documents/cicads/cicads/cidad45.htm). EPA assumes that the reference to the ICCA/HPV submission in the test plan refers to the OECD SIDS Dossier for the Ethylene Glycols category. The finalized SIDS Dossier is not yet available on the OECD website (http://cs3-hq.oecd.org/scripts/hpv/) but the chromosomal aberrations study mentioned in the Dossier (NTP Toxicology and carcinogenesis studies of ethylene glycol in B6C3F1 mice, 1993, Natl Toxicol Program Tech Rep Ser, Feb; 413:1-177) can be summarized for this endpoint and included in the IUCLID Data Set for the sponsored substance.

Ecological Effects (fish, invertebrate and algae)

EPA agrees that there are adequate data for invertebrates for the purposes of the HPV Challenge Program. EPA reserves judgement on the adequacy of the submitted ethylene glycol data for the fish and algae toxicity endpoints pending the submission of data for ethylene carbonate stability in water; testing of ethylene carbonate in fish and algae could be necessary (the submitted data for cyanobacteria do not address the algal toxicity endpoint). The submitter needs to address deficiencies in the robust summary for invertebrate toxicity.

Specific Comments on Robust Summaries

General

In general, the robust summaries did not provide enough details. The submitter should consult EPA guidance documents for the preparation of robust summaries: http://www.epa.gov/chemrtk/pubs/general/guidocs.htm.

Environmental Fate

Fugacity. The submitter has added "(Fugacity Model Level I)" next to each calculated value. However, the Type field indicates that the calculations follow Fugacity Model Level III. The submitter needs to delete the "(Fugacity Model Level I)" statements.

Ecological Effects

Invertebrates. The robust summary is of poor quality and needs to be enhanced to enable an independent evaluation of the submitted data. Critical data elements missing include: DO, pH, water hardness, water
temperature, chemical purity, number of replicates, number of organisms per replicate, and type of test.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.